

**Remarks**

**A. Pending Claims**

Claims 15, 21, 27, 34, 39, and 50 are amended. Claims 51-54 are new. Claims 15-39 and 41-54 are pending.

**B. Examiner Interview Summary Pursuant to 37 C.F.R. § 1.133(b)**

On June 2, 2010, Examiner Schillinger and attorney for Applicant (Chris Drymalla, Reg. No. 61,843) participated in a telephone interview to discuss certain rejections of the claims. During the teleconference, Applicant agreed to amend certain claim language to further clarify certain features of the claims. As a result of the teleconference, Examiner Schillinger requested that Applicant file a response including amendments to the claims.

**C. The Claims are Supported by the Written Description in Accordance with 35 U.S.C. §112**

In the Office Action, claims 27-34, 37, 38, 43, 48 and 49 are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. More specifically, the Office Action states:

The specification does not adequately explain how the expansion member lowers the support surface of the first insert below and away from the inferior surface of the cage element.

(Office Action, page 2)

Applicant respectfully disagrees. Applicant submits that the claimed combination of features is disclosed at least at FIG. 12i and page 24, line 6 to page 25, line 10 of Applicant's specification. Accordingly, Applicant submits that claims 27-34, 37, 38, 43, 48 and 49 comply with the written description requirement under 35 U.S.C. §112. Applicant respectfully request removal of the rejection.

**D. The Claims are Not Anticipated by Vaccaro under 35 U.S.C. §102(b)**

In the Office Action, claims 15-17, 19-23, 25-29, 32-34, 39 and 41-50 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Pat. No. 6,102,950 to Vaccaro (“Vaccaro”). Applicant respectfully submits that the claims are allowable over the cited art for at least the following reasons.

The standard for “anticipation” is one of fairly strict identity. A claim can only be anticipated if each and every element set forth in the claims is found to be either expressly or inherently described in the cited art. *Verdegaal Bros. V. Union Oil Co. of California*, 814 F.2d 728, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987), MPEP §2131. “All words in a claim must be considered in judging the patentability of that claim against the prior art.” *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970), MPEP 2143.03.

#### Independent Claim 15

Amended claim 15 describes a combination of features, including but not limited to:

an insert comprising a support surface for the second vertebra, wherein the support surface, during use, supports at least a portion of the second vertebra above and away from the superior surface of the cage element and inhibits movement of the second vertebra towards the first vertebra, and wherein the insert, during use, is inserted at least partially into the cage element; and

an expansion member that, during use, is inserted in the cage element through an opening in a side of the cage element to expand the intervertebral implant by elevating the insert to move a portion of the insert through the first opening in the superior surface of the cage element so that at least a portion of the support surface of the insert is raised above and away from the superior surface of the cage to support at least a portion of the second vertebra above and away from the superior surface of the cage element.

Vaccaro does not appear to disclose at least the above quoted features in combination with other features of claim 15.

With respect to claim 15, the Office Action states:

Vaccaro discloses the following of claim 15: an intervertebral implant for a human spine, comprising: a cage element (20) comprising a superior surface and an inferior surface (Fig. 2), wherein the inferior surface of the cage element is configured to support a first vertebra of the human spine

to inhibit movement of the first vertebra towards a second vertebra, and wherein the superior surface of the cage element comprises a first opening; an insert (50) comprising a support surface for the second vertebra, wherein the support surface configured to, during use, supports at least a portion of the second vertebra above and away from the superior surface of the cage element and inhibits movement of the second vertebra towards the first vertebra, and wherein the insert, during use, is configured to be positioned at least partially in the cage element; and an expansion member (40) configured to be that, during use, is inserted in the cage element through an opening (70) in a side of the cage element to expand the intervertebral implant by elevating the insert to move a portion of the insert through the first opening in the superior surface of the cage element so that at least a portion of the support surface of the insert is raised relative to the inferior above and away from

the superior surface of the cage to support at least a portion of the second vertebra above and away from the superior surface of the cage element (col. 6, lines 27-41; col. 7, lines 15-64).

(Office Action, pages 2-3)

Vaccaro discloses an intervertebral body fusion device having a wedge body, a cage component with a plurality of deployable spines having end plate penetrating teeth, and a contraction mechanism for drawing the wedge body into the cage component. (Vaccaro, abstract). In its final surgically-implanted position, the wedge body is substantially fully drawn within the cage component, resulting in a full deployment of teeth and associated spines into the adjacent end plates of the vertebral bodies. (Vaccaro, abstract). A cage component 20 includes a rigid upper member 22 defining a bearing surface 22a and an opposing interior surface 22b, and, a rigid lower member 24 also defining both a bearing surface 24a and an opposing interior surface 24b. (Vaccaro, col. 5, lines 32-35). The cage includes spines 50 integrally formed to depend from either an upper member 22 or a lower member 24. (Vaccaro, col. 6, lines 37-39). Each spine 50 has at least one tooth 52 facing outwardly at the free end 54, the tooth preferably forming a penetrating tip or spike. (Vaccaro, col. 6, lines 39-41). During use, each tooth 52 is fully deployed beyond an associated bearing surface 22a, 24a. (Vaccaro, col. 7, lines 28-29). Accordingly, Vaccaro appears to disclose an integral portion of the cage component 20 that includes teeth that are deployed beyond bearing surfaces such that the teeth penetrate into adjacent endplates of vertebral bodies. Vaccaro, however, does not disclose an insert that is inserted at least partially into the cage element during use. Moreover, the portion of cage component 220 that extends beyond the surfaces of the cage component include teeth that

penetrate the vertebral bodies, and do not support the vertebral body away from the surface of the cage component. Thus, the bearing surfaces (e.g., those surfaces that support the vertebra) appear to be the surfaces of the cage component (e.g., See Vaccaro FIG. 1). Vaccaro, thus, also does not appear to disclose a support surface of the insert that is raised above and away from the superior surface of the cage to support at least a portion of the second vertebra above and away from the superior surface of the cage element. The other cited art does not appear to remedy these deficiencies. Accordingly, Vaccaro taken alone or in hypothetical combination with the other cited art does not teach or suggest at least the features of, “an insert comprising a support surface for the second vertebra, wherein the support surface, during use, supports at least a portion of the second vertebra above and away from the superior surface of the cage element and inhibits movement of the second vertebra towards the first vertebra, and wherein the insert, during use, is inserted at least partially into the cage element,” and “an expansion member that, during use, is inserted in the cage element through an opening in a side of the cage element to expand the intervertebral implant by elevating the insert to move a portion of the insert through the first opening in the superior surface of the cage element so that at least a portion of the support surface of the insert is raised above and away from the superior surface of the cage to support at least a portion of the second vertebra above and away from the superior surface of the cage element,” in combination with other features of the claim.

For at least these reasons, Applicant respectfully submits that claim 15 is allowable over the cited art.

#### Independent Claim 21

Amended claim 21 describes a combination of features, including but not limited to:

an insert comprising an inferior surface and a support surface for the second vertebra, wherein the support surface, during use, supports the at least a portion of the second vertebra above and away from the superior surface of the cage element and inhibits movement of the second vertebra towards the first vertebra, wherein the insert, during use, is inserted at least partially into the cage element such that at least a portion of the inferior surface of the insert is below the superior surface of the cage element and at least a portion of the support surface of the insert is above the superior surface of the cage element to

support at least a portion of the second vertebra above and away from the superior surface of the cage element; and  
an expansion member that, during use, is inserted in the cage element through an opening in a side of the cage element to elevate at least a portion of the insert through the opening in the superior surface of the cage element so that the support surface of the insert is raised above and away from the superior surface of the cage to support at least a portion of the second vertebra above and away from the superior surface of the cage element

For at least reasons similar to those discussed above, Applicant submits that claim 21 is allowable over the cited art. Moreover, Applicant submits that Vaccaro does not appear to disclose the feature of, “wherein the insert, during use, is inserted at least partially into the cage element such that at least a portion of the inferior surface of the insert is below the superior surface of the cage element and at least a portion of the support surface of the insert is above the superior surface of the cage element to support at least a portion of the second vertebra above and away from the superior surface of the cage element,” in combination with other features recited by claim 21.

For at least these reasons, Applicant submits that claim 21 is allowable over the cited art.

#### Independent Claim 27

Amended claim 27 describes a combination of features, including but not limited to:

a first insert, wherein, during use, at least a portion of the first insert is inserted at least partially into the first opening, and wherein the first insert comprises a support surface that, during use, supports at least a portion of a first vertebra below and away from the inferior surface of the cage element and inhibits movement of the first vertebra towards a second vertebra;

a second insert, wherein, during use, at least a portion of the second insert is inserted at least partially into the second opening, and wherein the second insert comprises a support surface that, during use, supports at least a portion of a second vertebra above and away from the superior surface of the cage element and inhibits movement of the second vertebra towards the first vertebra; and

an expansion member that, during use, is inserted in a third opening in the cage element to lower the support surface of the first insert below and away from the inferior surface of the cage element to support at least a portion of the first vertebra below and away from the inferior surface

of the cage element and inhibit movement of the first vertebra towards a second vertebra,  
wherein the expansion member when inserted in the third opening raises the support surface of the second insert above and away from the superior surface of the cage element to support at least a portion of the second vertebra above and away from the superior surface of the cage element and inhibit movement of the second vertebra towards the first vertebra.

For at least reasons similar to those discussed above, Applicant submits that claim 27 is allowable over the cited art.

#### Independent Claim 39

Amended claim 39 describes a combination of features, including but not limited to:

a cage comprising a first opening in a superior surface of the cage and a second opening in an inferior surface of the cage, wherein, during use, the first member is inserted at least partially into the first opening and the second member is inserted at least partially in the second opening; and

an expansion element that, during use, is inserted between the first inferior surface of the first member and the second superior surface of the second member, wherein insertion of the expansion member expands the first and second members relative to one another to increase a separation distance between the first superior surface of the first member and the second inferior surface of the second member, wherein the first superior surface is expanded above the superior surface of the cage and the second inferior surface is expanded below the inferior surface of the cage, such that the distance between the first superior surface and the second inferior surface is greater than the distance between the superior surface and the inferior surface of the cage, and wherein the first superior surface supports at least a portion of the first vertebra above the superior surface of the cage and the second inferior surface supports at least a portion of the second vertebra below the inferior surface of the cage.

For at least reasons similar to those discussed above, Applicant submits that claim 39 is allowable over the cited art.

#### Independent Claim 50

Amended claim 50 describes a combination of features, including but not limited to:

a cage element implanted between a first vertebra and a second vertebra during use, wherein the cage element comprises a first surface facing the first vertebra and a second surface facing the second vertebra when implanted; and  
an insert that is configured to be inserted at least partially into the cage element for supporting the first vertebra in a position away from the first surface of the cage element.

For at least reasons similar to those discussed above, Applicant submits that claim 50 is allowable over the cited art.

#### Dependent Claims

Applicant also submits that several of the dependent claims are allowable based on the combination of features contained therein, in addition to the combination of features of their respective base claims. For example, the cited art does not teach or suggest at least the combination of feature of claim 41, including: “The intervertebral implant of claim 15, wherein the support surface comprises a substantially planar surface that supports at least a portion of the second vertebra above and away from the superior surface of the cage element and inhibits movement of the second vertebra towards the first vertebra during use.” Accordingly Applicant submits that claim 41 is allowable over the cited art. Applicant also submits that claims 42 and 43 are allowable over the cited art for similar reason.

As a further example, the cited art does not teach or suggest at least the combination of feature of claim 45, including: “The intervertebral implant of claim 15, wherein, during use, the support surface of the insert supports the second vertebra above and away from the superior surface of the cage element such that the second vertebra does not contact the superior surface of the cage element.” Accordingly Applicant submits that claim 45 is allowable over the cited art. Applicant also submits that claims 47 and 49 are allowable over the cited art for similar reason.

#### **E. The Claims Are Not Obvious over Vaccaro in view of Sertich under 35 U.S.C. §103(a)**

In the Office Action, claims 18, 24, 30, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vaccaro in view of U.S. Pat. No. 5,800,550 to Sertich (“Sertich”).

Applicant submits that claims 18, 24, 30 and 31 are patentable over the cited art for at least reasons similar to those discussed above.

**F. New Claims**

New claim 51 recites a combination of features including: "The intervertebral implant of claim 15, wherein the expansion member, during use, is at least partially removed from the cage element after being inserted in the cage element through an opening in a side of the cage element to expand the intervertebral implant." Applicant submits that at least these features, in combination with other features of the claim, are not taught or suggested by the prior art.

New claim 52 recites a combination of features including: "The intervertebral implant of claim 21, wherein the expansion member, during use, is at least partially removed from the cage element after being inserted in the cage element through the opening in a side of the cage element to elevate at least a portion of the insert." Applicant submits that at least these features, in combination with other features of the claim, are not taught or suggested by the prior art.

New claim 53 recites a combination of features including: "The intervertebral implant of claim 27, wherein the expansion member, during use, is at least partially removed from the cage element after being inserted in the third opening in the cage element to lower the support surface of the first insert below and away from the inferior surface of the cage element to support at least a portion of the first vertebra below and away from the inferior surface of the cage element and inhibit movement of the first vertebra towards a second vertebra." Applicant submits that at least these features, in combination with other features of the claim, are not taught or suggested by the prior art.

New claim 54 recites a combination of features including: "The intervertebral implant of claim 39, wherein the expansion element, during use, is at least partially removed from the cage element after being inserted between the first inferior surface of the first member and the second superior surface of the second member." Applicant submits that at least these features, in combination with other features of the claim, are not taught or suggested by the prior art.

**G. Additional Comments**

Applicant submits that all claims are in condition for allowance. Favorable consideration is respectfully requested.

If an extension of time is required, Applicant hereby requests the appropriate extension of time. If any other fees are required, or have been overpaid, please appropriately charge those fees to Meyertons, Hood, Kivlin, Kowert & Goetzel, P.C. Deposit Account Number 50-1505/5943-00300/EBM.

Respectfully submitted,

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